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MICHAEL RODAK, JR., C

No. 73-168

In the Supreme Court of the United States

OCTOBER TERM, 1973

MARKO DUROVIC, an individual and also known as MARKO DUROVIC, formally d/b/a DUGA LABORATORIES; STEVAN DUROVIC, d/b/a PROMAK LABORATORIES; and KREBIOZEN RESEARCH FOUNDATION, a corporation,

Petitioners,

VS.

CASPAR W. WEINBERGER, Secretary of Health, Education & Welfare, and ALEXANDER M. SCHMIDT, Commissioner of Food & Drugs,

Respondents.

PETITION FOR REHEARING OF ORDER DENYING PETITION FOR WRIT OF CERTIORARI

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Respondents.

PETITION FOR REHEARING

Petitioners present their petition for a rehearing of this Court's order dated October 15, 1973, denying the petition for a Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit, and, in support thereof, respectfully show:

GROUNDS FOR REHEARING

This Court, on October 15, 1973, denied petitioner's request for Certiorari, and let stand a decision granting the government's motion for summary judgment, and denying

petitioner's motion for summary judgment. The two issues raised by plaintiffs' complaint were, whether the drug Krebiozen was a "new drug" under the Food, Drug & Cosmetic Act, 21 U.S.C., Section 355, and whether a New Drug Application was presently effective for Krebiozen under that statute. An affirmative answer to either issue would have permitted the petitioner to market the drug in interstate commerce. In all of this time, however, petitioners presumed they would have the right to distribute the drug on a physician's recommendation in intrastate commerce; that is, within the State of Illinois.

However, on September 7, 1973, since the filing of petitioner's request for Writ of Certiorari, the Illinois legislature has amended the Illinois Food, Drug & Cosmetic Act to prohibit the selling or giving away of any "new drug" in Illinois, unless a New Drug Application has been approved under Section 505 of the Federal Act, exempting "any drug which is not a new drug as defined in the Federal Act." (See Illinois Public Act 75-599, Laws 1973, attached hereto.)

By refusing to grant petitioners a trial on the merits, this Court has not only prevented Krebiozen from moving in interstate commerce, but it has also, apparently, made distribution of the product illegal within Illinois *even where its use is recommended by a learned physician.*

The significance of this is that individuals who are present or past cancer patients, and who had been introduced to Krebiozen by their physicians can no longer continue to receive the drug in Illinois, in situations wherein the physician and patient believe the very life of the patient to be dependent upon a supply of the drug.

We have contended that the Seventh Circuit erred in not giving Plaintiff the opportunity to present evidence concerning general recognition of safety of the drug.

In the case of *Free* v. *Bland*, 369 U.S. 603, the Court decided that controverted allegations could only be resolved by trial on merits, not summary judgment.

We also urge that a grant of motion for summary judgment is often inappropriate where evidence bearing on crucial issues of fact is in the form of expert opinion testimony.

The Seventh Circuit stated:

> "We have been made aware, in this record of much of the emotionally charged controversy about Krebiozen. Some characterize Krebiozen as a hoax, yet there are many who believe with deep sincerity that a number of cancer sufferers have been aided, or even saved by it. Its advocates contend that the medical "establishment" both in and out of government has unfairly denied Krebiozen a reasonable test. So distinguished a person as the Honorable Paul Douglas, former Senator from Illinois has taken its part."

That Court by this admits the existence of genuine issues of material fact and the existence of controverted allegations, but denies the Plaintiff a day in Court and a hearing on genuine and substantial questions of fact.

In support of this question of fact we will mention only some of these opinions and reports which are contained in the record:

1.) Reports, clinical histories and opinion of 4,277 patients by about 3,000 licensed physicians, collated by Dr. A. C. Ivy. (Exhibit No. 4)

2.) Affidavit of Dr. A. C. Ivy of March 30, 1971 that the Krebiozen is safe and beneficial in the treatment of cancer.

3.) Affidavits of licensed physicians from April 1954 who used Krebiozen that the drug is safe in the management of cancer. (Exhibit No. 5)

4.) Affidavits of licensed physicians from March 1961 who used Krebiozen that the drug is safe in the management of cancer.

5.) Comments and opinions of One-hundred prominent physicians who used Krebiozen and found that the drug is safe and beneficial in the treatment of cancer. Among them are: DR. WALLACE GRAHAM, Major General and then Chief-of-Surgery in Walter Reed Hospital and Personal physician of President of the United States; DR. CHARLES BARRETT, Professor of Therapeutic Radiology Col. of Medicine Cincinnati and Director of the Tumor Clinic; DR. HUGH FULCHER, Professor of Neurosurgery, School of Medicine, Georgetown University and Chief Surgeon Grace Hospital Welsh, West Virginia; HENRY JAFFE, Professor of Pathology, New York Medical College; DR. VICTOR JOHNSON, Director of Mayo Graduate School of Medicine, Professor of Physiology, etc.; DR. CHARLES JOHNSON, Associate Professor of Clinical Pathology, Medical College of Virginia; DR. H. L. KAPLAN, Associate Professor of Internal Medicine, College of Medicine, Baylore; DR. LOUIS KRASNO, Assistant Professor Department of Medicine, Stanford; DR. WILLIAM M. LEES, Associate Professor Thoracic Surgery, Stritch School of Medicine, Loyola University; DR. H. C. LUETH, Clinical Professor College of Medicine, Illinois; DR. ALICE E. MOORE, Associate Professor of Biology, Sloan-Kettering Division, Cornell, Assistant and

Head of Sloan-Kettering Institute for Cancer Research; DR. LEON ARIES; DR. L. PAUL RALPH, Attending physician of the late Senator Arthur Vandenberg.

6.) Report of the Institute for Cancer Research and Lankenau Hospital Research Institute of Philadelphia (Ex. 23 to Plaintiffs' Reply Affidavit, submitted March 30, 1971), a leading cancer research institute whose reputation is known not only in the United States, but throughout the world. Experiments and observations were conducted by two prominent scientists, DR. STANLEY REIMANN and DR. THOMAS POMEROY on 40 patients, and they concluded:

> "Our conclusions on the material to date, though quite preliminary, are that it (Krebiozen) is non-toxic per se and has definite biologic activity specifically against tumor cells either directly or indirectly, or sufficient degree to warrant continued investigation of its mode of action with the hope that improvements may be made or some further knowledge concerning the biologic factors, controlling tumor growth may be contributed. Since this represents the first and only non-toxic chemical agent to show definite biologic activity of any degree against tumors of many types, it seems justifiable to encourage as much basic and clinical investigation as possible . . ."

Over this evidence, the Seventh Circuit Court chose to superimpose two affidavits, one of Dr. Jesse Steinfeld, Surgeon General and other of Dr. Carl Baker, Director of National Cancer Institute neither of whom ever used Krebiozen (Statement of Jesse Steinfeld in the Krebiozen trial, transcript page 9575, Ex. 21).

Dr. Steinfeld is an internist ("I was Board Certified in Internal Medicine in 1958"—Government Ex. 12.). Dr. Baker is a general practitioner ("I was licensed to practice

Medicine in the State of California"—Government Ex. 12). Neither Dr. Steinfeld nor Dr. Baker are cancer experts, because there is no board of experts in the field of cancer.

Their statements are negative statements and as such should not prevail over positive and credible testimony.

The Seventh Circuit opinion may now be *res judicata* in any future action which petitioners may wish to bring in the state courts of Illinois, with respect to the interpretation of "new drug" under the Illinois Act.

The issue, therefore, is one of life and death to those who are obtaining Krebiozen from physicians in Illinois and leads counsel to believe that it provides a sufficient basis for this Court to reconsider its denial of the petition for a Writ of Certiorari.

CONCLUSION

For the foregoing reasons, it is respectfully requested that this petition for rehearing be granted, and that upon further consideration, Writ of Certiorari issue to the United States Court of Appeals for the Seventh Circuit.

Respectfully submitted,

/s/ Solomon H. Friend
Solomon H. Friend
Attorney for Petitioners

Dated: New York, New York.

November, 1973.

CERTIFICATE OF COUNSEL

I, Solomon H. Friend, counsel for the above-named petitioner, do hereby certify that the foregoing petition for rehearing is presented in good faith and not for delay, and that it is restricted to the grounds specified in Rule 58 Subdivision 2 of the Rules of this Court.

/s/ *Solomon H. Friend*
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